OCT 19 2004 K040839

510(k) SUMMARY

COMPLETE® BLINK-N-CLEAN® Lens Drops

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

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Regulatory Affairs
Advanced Medical Optics
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Summary Prepared: September 30, 2004

(a)(2) **Device Trade Name:** COMPLETE® BLINK-N-CLEAN® Lens Drops

Device Common Name: Soft (Hydrophilic) and Rigid Gas Permeable Contact Lens Solution

Device Classification/Panel: Class II (Special Controls)/Ophthalmic Device

Device Classification Names: Accessories, Soft Lens Products (LPN) Products, Contact Lens Care, Rigid Gas Permeable (MRC)

(a)(3) **Identification of Predicate Device:** COMPLETE® BLINK-N-CLEAN® Lens Drops is the same as the currently-marketed lens drops and substantially equivalent to other lubricating and rewetting drop products.

(a)(4) **Device Description:** COMPLETE® BLINK-N-CLEAN® Lens Drops is a sterile, isotonic, buffered, solution containing lubricants, preservatives, buffers, surfactants, ancillary ingredients, and purified water.

The product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use):** COMPLETE® BLINK-N-CLEAN® Lens Drops is indicated to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses, as well as rigid gas permeable lenses before application and during wear.

(a)(6) **Comparison of Technological Characteristics:** The technological characteristics of the product remain the same.

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(b)(1) **Discussion of Nonclinical Studies:**

COMPLETE®BLINK-N-CLEAN® Lens Drops was evaluated for compatibility with silicone acrylate lenses and fluorosilicone acrylate rigid gas permeable (RGP) lenses during thirty (30) regimen cycles. Average changes in diameter, power and base curve for the test lenses were within established acceptance criteria, with test lenses showing a trend comparable to that of the controls. In addition, visual observations did not show evidence of surface deposits, discoloration and/or deformities. Based on these results, COMPLETE® BLINK-N-CLEAN® Lens Drops is compatible with all RGP contact lenses.

In addition, a study for quantifying surface protein accumulation on human-worn contact lenses and subsequent protein removal in simulated in-eye use of lens rewetter products has been conducted. The results show that COMPLETE® BLINK-N-CLEAN® Lens Drops removal significant amount of protein than the predicate devices.

Other preclinical safety and efficacy criteria were established in P910075/S7.

(b)(2) **Clinical:**

Clinical safety and acceptability of COMPLETE® BLINK-N-CLEAN® Lens Drops was established in 910075/S7.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** The safety, efficacy and performance of COMPLETE® BLINK-N-CLEAN® Lens Drops is substantially equivalent to other contact lens care lubricating and rewetting drops currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

Advanced Medical Optics
c/o Mr. Paul Nowacki
Manager, World Regulatory Affairs and Medical Compliance
1700 E. St. Andrew Place
P.O. Box 25162
Santa Ana, CA 92799-5162

Re: K040839
Trade/Device Name: Complete® Blink-N-Clean® Lens Drops
Regulation Number: 21 CFR 886.5918; 21 CFR 886.5928
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC; LPN
Dated: August 13, 2004
Received: August 17, 2004

Dear Mr. Nowacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: _____
(IF KNOWN):

DEVICE NAME: COMPLETE® BLINK-N-CLEAN® Lens Drops

INDICATIONS FOR USE:

- COMPLETE® BLINK-N-CLEAN® Lens Drops is indicated to lubricate and rewet soft (hydrophilic) contact lenses, disposable lenses and extended wear lenses, as well as rigid gas permeable lenses before application and during wear.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices

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